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In Re Application of: Clark R. Baker Jr.	§	Group Art Unit:	3735
Serial No.: 10/796,566	§	Confirmation No.:	1089
Filed: March 8, 2004	§	Examiner:	Toth, Karen E.
For: PULSE OXIMETER WITH ALTERNATE HEART-RATE DETERMINATION	§	Atty. Docket:	TYHC:0069/FLE/BAK P0426R 009103-022600US

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December 7, 2007 — Date
Leah Espinosa — Leah Espinosa

APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 41.31 AND 41.37

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on October 2, 2007, and received by the Patent Office on October 9, 2007.

The Commissioner is authorized to charge the requisite filing fee of $510.00, and any additional fees that may be required, to the credit card listed on the attached PTO-2038. However, if the PTO-2038 is missing, if the amount listed thereon is insufficient, or if the amount is unable to be charged to the credit card for any other reason, the Commissioner is authorized to charge Deposit Account No. 06-1315; Order No. TYHC:0069/FLE (P0426R).

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1. **REAL PARTY IN INTEREST**

The real party in interest is Nellcor Puritan Bennett LLC, the Assignee of the above-referenced application by virtue of the Assignment to Nellcor Puritan Bennett LLC recorded at reel 015591, frame 0811 and dated July 23, 2004. Accordingly, Nellcor Puritan Bennett LLC, as successor of the Assignee of the above-referenced application, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 1-13 are currently pending, and claims 1-13 are currently under final rejection and, thus, are the subject of this Appeal.

4. **STATUS OF AMENDMENTS**

Appellants have not submitted any amendments subsequent to the Final Office Action mailed on July 2, 2007. Therefore, there are no outstanding amendments to be considered by the Board.

5. **SUMMARY OF CLAIMED SUBJECT MATTER**

The application includes four independent claims, namely, claims 1, 5, 8, and 11, all of which are the subject of this Appeal. The subject matter of these claims is summarized below.

With regard to the aspect of the invention set forth in independent claim 1, discussions of the recited features of claim 1 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments determining a first heart rate from a pulse oximetry signal using a first method. *See, e.g.*,

Application, paragraphs [0067]-[0071]; Fig. 3. Further, present embodiments include determining a second heart rate from the pulse oximetry signal using a second method. *See, e.g.*, Application, paragraphs [0067]-[0071]; Fig. 3. Present embodiments also include evaluating a reliability of the first heart rate using metrics applied to the first method; using the first heart rate when the metrics indicate the first method is reliable; and using the second heart rate when the metrics indicate that the first heart rate is unreliable. *See, e.g.*, Application, paragraphs [0015], [0067]-[0071]; Fig. 3.

With regard to the aspect of the invention set forth in independent claim 5, discussions of the recited features of claim 5 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include a first heart rate calculator for determining a first heart rate from a pulse oximetry signal using a first method. *See, e.g.*, Application, paragraphs [0015], [0067]-[0071]; Fig. 3. Further, present embodiments include a second heart rate calculator for determining a second heart rate from the pulse oximetry signal using a second method. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3. Present embodiments also include an evaluator configured to determine the reliability of the first heart rate using metrics applied to the first method a selector configured to use the first heart rate when the metrics indicate said first method is reliable, and to use the second heart rate when the metrics indicate that the first heart rate is unreliable. *See, e.g.*, Application, paragraphs [0015], [0067]-[0071]; Fig. 3

With regard to the aspect of the invention set forth in independent claim 8, discussions of the recited features of claim 8 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include a sensor adapted to provide a signal related to a physiological constituent. *See, e.g.*, Application, paragraphs [0006], [0007], [0019], Fig. 1. Further, present embodiments include a monitor adapted to process the signal to determine a pulse period. *See, e.g.*, Application, paragraphs [0006], [0007], [0019], Fig. 1. Further, present embodiments include software adapted to determine a first pulse period from the signal

using a first method. *See, e.g.*, Application, paragraphs [0067]-[0071]; Fig. 3. Present embodiments also include software adapted to determine a second pulse period from the signal using a second method an evaluator configured to determine the reliability of the first pulse period using metrics applied to the first method. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3. Present embodiments also include a selector configured to use the first pulse period when the metrics indicate the first method is reliable, and to use the second pulse period when the metrics indicate that the first pulse period is unreliable. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3.

With regard to the aspect of the invention set forth in independent claim 11, discussions of the recited features of claim 11 can be found at least in the below cited locations of the specification and drawings. By way of example, present embodiments include determining a first pulse period from a pulse oximetry signal using a first method. *See, e.g.*, Application, paragraphs [0067]-[0071]; Fig. 3. Further, the pulse oximeter sensor may comprise evaluating a reliability of the first pulse period using metrics. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3. Additionally, present embodiments may include determining a second pulse period from the pulse oximetry signal using a second method when the metrics indicate that the first pulse period is unreliable. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3. Further, the pulse oximeter sensor may comprise converting the first pulse period into a heart rate when the metrics indicate that the first pulse period is reliable. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3. Further, the pulse oximeter sensor may comprise converting the second pulse period into a heart rate when the metrics indicate that the first pulse period is unreliable. *See, e.g.*, Application, paragraphs [0015], [0032], [0067]-[0071]; Fig. 3.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

First Ground of Rejection:

Appellants respectfully urge the Board to review and reverse the Examiner's ground of rejection in which the Examiner rejected claims 1, 5, 8, 10, and 11 under 35 U.S.C. § 102, as being anticipated by the Diab reference (U.S. Patent Application Publication 2002/0128544).

Second Ground of Rejection:

Appellants also respectfully urge the Board to review and reverse the Examiner's ground of rejection in which the Examiner rejected claims 2, 6, and 12 under U.S.C. §103(a) as being unpatentable over the Diab reference in view of the Leon reference (US Patent No. 5,365,934).

Third Ground of Rejection:

Appellants finally respectfully urge the Board to review and reverse the Examiner's ground of rejection in which the Examiner rejected claims 3, 4, 7, 9, and 13 under U.S.C. §103(a) as being unpatentable over the Diab reference in view of the Baker reference (US Patent Application Publication 2002/0137994).

7. ARGUMENT

As discussed in detail below, the Examiner has improperly rejected the pending claims. Further, the Examiner has misapplied long-standing and binding legal precedents and principles in rejecting the claims under 35 U.S.C. § 102 and 35 U.S.C. § 103. Accordingly, Appellants respectfully request full and favorable consideration by the Board, as Appellants strongly believe that claims 1-13 are currently in condition for allowance.

A. **First Ground of Rejection:**

The Examiner rejected claims 1, 5, 8, 10, and 11 under 35 U.S.C. § 102 as being anticipated by the Diab reference (U.S. Patent Application Publication 2002/0128544) in the Office Action mailed July 2, 2007. The Appellants respectfully urge the Board to reverse this rejection in view of the reasons set forth below.

In the rejection, the Examiner stated the following:

> Regarding claim 1, Diab discloses a method comprising using a first and a second method to determine the first and second heart rates from a pulse oximetry signal (paragraphs [0028], [0257], [0327]), evaluating the reliability of the first heart rate using metrics (paragraph [0322]-High Confidence Test Module 301), and using the first heart rate when the metrics indicate that the first method is reliable and using the second heart rate when the metrics indicate that the first method is unreliable (paragraphs [0328]-[0332], [0345]-[0347]-that is, the results of the confidence test is used to determine which method of signal processing is used to find the heart rate.
>
> Regarding claim 5, Diab discloses a pulse oximeter that can be used to determine a heart rate (paragraphs [0019]-[0020], [0028]) comprising first and second heart rate calculators for determining first and second heart rates from a pulse oximetry signal using first (element 586) and second (element 590) methods (paragraphs [0257], [0327]-[0332]), an evaluator configured to determine the reliability of the first heart rate by applying metrics to the first method (High Confidence Test Module 301-paragraph [0322]), and a selector configured to use the first heart rate when the metrics indicate that the first method is reliable and the second heart rate when the metrics indicate that the first method is unreliable.
>
> Regarding claims 8 and 10, Diab discloses a pulse oximetry system comprising a sensor adapted to provide a signal related to a physiological constituent (element 300; paragraphs [0019]-[0020], [0028]) and a monitor adapted to process the signal to determine a pulse period, the monitor comprising software adapted to process the signal to determine a first pulse period using a first method (element 586), software adapted to process the signal to determine a second pulse period using a second method (element 590), an evaluator configured to determine the reliability of the first heart rate by applying metrics to the first method (element 301),and a selector configured to use the first heart rate when the metrics

> indicate that the first method is reliable and the second heart rate when the metrics indicate that the first method is unreliable (paragraphs [0327]-[0332], [0345]-[0347]). Diab's method converts a frequency spectrum, or pulse period, to a pulse rate.
>
> Regarding claim 11, Diab discloses method of determining a heart rate in a pulse oximeter (element 300; paragraphs [0019]-[0020], [0028]) comprising determining a first pulse period from a pulse oximetry signal using a first method (element 586) and second pulse period from a pulse oximetry signal using a second method (element 590) when the metrics (element 301) indicate that the first method is unreliable, and converting the first pulse period into a heart rate when the metrics indicate that it is reliable and converting the second pulse period into a heart rate when the metrics indicate that the first is unreliable (paragraphs [0327]-[0332], [0345]-[0347]).
>
> Office Action mailed July 2, 2007, page 2-3.

Anticipation under Section 102 can be found only if a single reference shows exactly what is claimed. *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 U.S.P.Q. 773 (Fed. Cir. 1985). For a prior art reference to anticipate under Section 102, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). To maintain a proper rejection under Section 102, a single reference must teach each and every element or step of the rejected claim. *Atlas Powder v. E.I. du Pont*, 750 F.2d 1569 (Fed. Cir. 1984). Thus, if the claims recite even one element not found in the cited reference, the reference does not anticipate the claimed invention.

The Diab reference fails to disclose the claimed element in claims 1, 5, 8, 10, and 11 of a second method of determining a heart rate. The Examiner has pointed to

elements 586 and 590 of the Diab reference as examples of first and second methods of determining a heart rate. The Examiner is correct that element 590 represents a spectral analysis module that outputs the initial heart rate determination. However, element 586 in the Diab reference does *not* represent a heart rate determination method. As shown in Fig. 20 of the Diab reference, there are two possible inputs to the spectral analysis module 590. A choice is made whether to use input 586 or input 588 based on the presence or absence of detected motion. These inputs represent a spectrum containing potential peaks *from which no heart rate has yet been determined.* Regardless of the choice of the spectral estimation input 586 or 588, the spectral analysis module 590 will perform *one method* of heart rate determination on the single selected input. Accordingly, the Diab reference does not disclose a second method of determining a heart rate.

The Diab reference also does not include a selector for choosing between a first heart rate and a second heart rate as recited in claims 5, 8, and 10. Because the spectrum analysis module 590 only calculates a single heart rate and does *not* calculate a second heart rate, the Diab reference does not disclose a selector or a selection step for choosing between a first heart rate and a second heart rate.

Further, the Diab reference fails to disclose an evaluator (claims 5, 8, and 10) and/or an evaluating step (claims 1 and 11) for determining the reliability of a first heart rate by applying metrics to the first method. The Examiner has pointed to paragraph

[0322] of the Diab reference as describing an evaluator that determines the reliability of a first heart rate. However, as recited in paragraph [0322], the High Confidence Test Module (element 570 in paragraph [0322]-not element 301 as noted by the Examiner) feeds into the oxygen saturation calculation, and not the heart rate determination module 590. As shown in Fig. 19 of the Diab reference, the output of the High Confidence Test Module is ultimately fed into the clip and smooth module 566, which provides the oxygen saturation values. The clip and smooth filter compares each new saturation value to previous saturation values according to preset parameters. The clip and smooth module 566 evaluates oxygen saturation values, *not* heart rate values. Accordingly, the Examiner is incorrect in stating that the results of the confidence test of the High Confidence Test Module are used to determine which method of signal processing is used to find the heart rate because the confidence test of Diab does not evaluate the reliability of heart rate values.

In the Advisory Action mailed September 27, 2007, the Examiner maintained the same rejection of claims as formulated in the Final Office Action. Specifically, the Examiner stated:

> Applicant argues that Diab (US 2002/0128544) does not disclose two methods of determining a heart rate. Diab clearly discloses separate methods of determining a heart rate-one in the case of no motion, and one in the case of motion (paragraphs [0327]-[0333]). Diab further discloses a selector for choosing a heart rate (analysis module-paragraphs [0332], [0345]) and evaluator for determining the reliability of the first heart rate (High Confidence Test Module 570, which is directed to determining patient motion any may be used for either oxygen saturation of heart rate determination-see paragraph [0334]).

Advisory Action mailed September 27, 2007, p. 2.

The Appellants disagree with the statements made by the Examiner in the Advisory Action. The Examiner has pointed to paragraphs [0327]-[0333] of the Diab reference as teaching two methods of determining heart rate. The Examiner is incorrect in stating that these paragraphs disclose two methods of determining a heart rate. As discussed above, the inputs to the spectral analysis module 590, referenced in paragraphs [0327]-[0333], represent a spectrum containing potential peaks *from which no heart rate has yet been determined.* Although the Examiner states that the choice of using an input based on detected motion or no detected motion represents two different methods of determining heart rate, only one method of determining heart rate is disclosed. In other words, the Examiner has attempted to equate the selection of one of two input signals from which a heart rate may be determined with two separate heart rate determinations using two different methods. Thus, the Examiner has again incorrectly characterized *a single method of determining heart that has two possible inputs* (motion vs. no motion) with two different methods of determining heart rate.

The Examiner is also incorrect in stating that Diab discloses a selector for choosing a heart rate (analysis module-paragraphs [0332]). Paragraph [0332] provides no reference to selecting between two different heart rates that are calculated by two different methods. According to paragraph [0332], a heart rate can be selected from a single spectrum. If a first harmonic from the spectrum is not satisfactory, a second harmonic can be selected. In the case of Diab, the heart rate is not selected from two

different heart rates that have been calculated by two different methods, but rather from a single input (*i.e.* a single frequency spectrum) *from which no heart rate has yet been determined.*

The Examiner is also incorrect in stating that the Diab reference discloses an evaluator for determining the reliability of the first heart rate. The Examiner has again pointed to the High Confidence Test Module 570 and paragraph [0334] as disclosing an evaluator for determining the reliability of a first heart rate. Paragraph [0334] discusses a motion artifact processor for processing saturation data. Appellants find no disclosure related to heart rate evaluation in paragraph [0334]. Paragraph [0334] states that the High Confidence Test Module 570 performs the same function as the reference processor. As discussed in paragraph [0289], the reference processor is part of the oxygen saturation transform module and, thus, is unrelated to heart rate determination. As noted above, the output of the High Confidence Test Module 570 also feeds into the oxygen saturation determination. Appellants maintain that there is no teaching of an evaluator for determining reliability of a calculated heart rate in Diab.

For at least these reasons, the Diab reference fails to anticipate claims 1, 5, 8, 10, and 11 under 35 U.S.C. § 102(b). Accordingly, The Applicant respectfully request withdrawal of the anticipation rejection.

B. **Second Ground of Rejection**

The Examiner rejected claims 2, 6, and 12 under 35 U.S.C. § 103(a) as being

unpatentable over the Diab reference in view of the Leon reference. Claim 2 is dependent upon independent claim 1, claim 6 is dependent upon independent claim 5, and claim 12 is dependent upon independent claim 11. The additional reference, the Leon reference, does not obviate the deficiencies of the other references discussed in detail above with regard to the first ground of rejection. As a result, the cited references, taken alone or in hypothetical combination, fail to teach or suggest the features of independent claims 1, 5, and 11 their dependent claims 2, 6, and 12, respectively. Appellants believe claims 2, 6, and 12 to be clearly allowable based upon virtue of dependency upon allowable base claims.

C. **Third Ground of Rejection**

The Examiner rejected claims 3, 4, 7, 9, and 13 under 35 U.S.C. § 103(a) as being unpatentable over the Diab reference in view of the Baker reference. Claims 3 and 4 are dependent upon independent claim 1, claim 7 is dependent upon independent claim 5, claim 9 is dependent upon independent claim 8, and claim 13 is dependent upon independent claim 11. The additional reference, the Baker reference, does not obviate the deficiencies of the other references discussed in detail above with regard to the first ground of rejection. As a result, the cited references, taken alone or in hypothetical combination, fail to teach or suggest the features of independent claims 1, 5, 8, and 11 their dependent claims 3 and 4, 7, 9, and 13, respectively. Appellants believe claims 3, 4, 7, 9, and 13 to be clearly allowable based upon virtue of dependency upon allowable base claims.

For at least the foregoing reasons, Appellants respectfully request reversal of the outstanding rejections and allowance of the pending claims.

Conclusion

Appellants respectfully submit that all pending claims are in condition for allowance. However, if the Examiner or Board wishes to resolve any other issues by way of a telephone conference, the Examiner or Board is kindly invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,

Date: December 7, 2007

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8. APPENDIX OF CLAIMS ON APPEAL

Listing of Claims:

1. A method for determining a heart rate in a pulse oximeter comprising:

determining a first heart rate from a pulse oximetry signal using a first method;

determining a second heart rate from the pulse oximetry signal using a second method;

evaluating a reliability of the first heart rate using metrics applied to the first method;

using the first heart rate when the metrics indicate the first method is reliable; and

using the second heart rate when the metrics indicate that the first heart rate is unreliable.

2. The method of claim 1 comprising

determining that the first heart rate is unreliable when the metrics indicate that a most recent pulse is rejected.

3. The method of claim 1 wherein the first method does not use an ensemble averaged waveform, and the second method does use an ensemble averaged waveform.

4. The method of claim 1 wherein determining a first and second heart rate each comprise determining a pulse period, and comprising:

converting a pulse period used into a rate.

5. A pulse oximeter which determines a heart rate, comprising:

a first heart rate calculator for determining a first heart rate from a pulse oximetry signal using a first method;

a second heart rate calculator for determining a second heart rate from the pulse oximetry signal using a second method;

an evaluator configured to determine the reliability of the first heart rate using metrics applied to the first method; and

a selector configured to use the first heart rate when the metrics indicate said first method is reliable, and to use the second heart rate when the metrics indicate that the first heart rate is unreliable.

6. The pulse oximeter of claim 5 wherein the selector determines that the first heart rate is unreliable when the metrics indicate that a most recent pulse is rejected.

7. The pulse oximeter of claim 5 wherein the first heart rate calculator does not use an ensemble averaged waveform, and the second heart rate calculator does use an ensemble averaged waveform.

8. A pulse oximetry system comprising:

a sensor adapted to provide a signal related to a physiological constituent; and

a monitor adapted to process the signal to determine a pulse period, the monitor comprising:

software adapted to determine a first pulse period from the signal using a first method;

software adapted to determine a second pulse period from the signal using a second method;

an evaluator configured to determine the reliability of the first pulse period using metrics applied to the first method; and

a selector configured to use the first pulse period when the metrics indicate the first method is reliable, and to use the second pulse period when the metrics indicate that the first pulse period is unreliable.

9. The system of claim 8 wherein the first method does not use an ensemble averaged waveform, and the second method does use an ensemble averaged waveform.

10. The system of claim 8 wherein the first pulse period or the second pulse period is converted into a heart rate.

11. A method for determining a heart rate in a pulse oximeter comprising:

determining a first pulse period from a pulse oximetry signal using a first method;

evaluating a reliability of the first pulse period using metrics;

determining a second pulse period from the pulse oximetry signal using a second method when the metrics indicate that the first pulse period is unreliable;

converting the first pulse period into a heart rate when the metrics indicate that the first pulse period is reliable; and

converting the second pulse period into a heart rate when the metrics indicate that the first pulse period is unreliable.

12. The method of claim 11 comprising

determining that the first pulse period is unreliable when the metrics indicate that a most recent pulse is rejected

13. The method of claim 11 wherein the first method does not use an ensemble averaged waveform, and wherein the second method does use an ensemble averaged waveform.

9. EVIDENCE APPENDIX

None.

10. **RELATED PROCEEDINGS APPENDIX**

None.